UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 26, 2010

MEMORANDUM

Subject: Efficacy Review for Anolite; EPA Reg. No. 85134-1; DP Barcode: D375287.

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

5/28/10

To: Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Envirocleanse LLC
14019 SW Freeway # 301-387
Sugar Land, TX 77478

Formulation from the Label:

Active Ingredient	% by wt.
Hypochlorous Acid	0.025 %
Other Ingredients:	99.975 %
Total	100.000 %

Contains 338 ppm Free Available Chlorine

I. BACKGROUND

The product, Anolite (EPA Reg. No. 85134-1), is an EPA-approved disinfectant, for use on hard, non-porous surfaces in commercial, household, hospital or medical environments. The applicant requested an amendment to the registration of this product to add disinfectant claims for effectiveness against Swine Influenza A Virus (H1N1). Testing was conducted by Microbiotest, Inc. located at 105B Carpenter Drive in Sterling Virginia

This data package contained a letter from the applicant representative to EPA (dated February 22, 2010), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), one study (MRID 479900-01), Statements of No Data Confidentiality Claims for the study, and the proposed label.

II. USE DIRECTIONS

The product is intended for use as a disinfectant in commercial, industrial, and household environments such as hotels, office buildings, restaurants, convenience stores, food processing plants, schools, playgrounds (indoor), day care centers, nursing homes, cafeterias, prisons, police stations, hospitals, pharmaceutical and medical device producing establishments, homes, condos, apartments, veterinarian clinics, and other facilities. The product is to be used on hard, non-porous surfaces such as countertops, sinks, toilets, tables, chairs, appliances desks, beds, floors, computer keyboards, door knobs, and similar surfaces.

The proposed label provides the following directions for use of the product as a disinfectant on hard, non-porous surfaces. Apply to surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. Remove gross soiling from surfaces before applying this product. Small non-porous objects can also be soaked in Anolite without dilution. Allow objects to soak for 10 minutes.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims: On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 479900-01 "Virucidal Efficacy Test Using Swine Influenza A Virus (H1N1)" for Anolite, by Steve Zhou. Study conducted at Microbiotest. Study completion date – October 30, 2009. Project Number 668-104.

This study was conducted against Swine influenza A virus (H1N1) (A/Swine/1976/31; ATCC VR-99), using MDCK cells (Madin-Darby Canine Kidney cells; ATCC CCL-34) as the host system. Two lots (Lot Nos. Oct 4, 2009 and Sept 25, 2009) of the product, Anolite, were tested according to Microbiotest Protocol No. 668.1.10.01.09 (copy provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes. For each lot of product, separate dried virus films were exposed to 2.00 mL of the product for 10 seconds at 20±1°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were diluted serially in Minimum Essential Medium supplemented with 1% fetal bovine serum, 1% HEPES, and 0.01 mol/L $NA_2S_2O_3$. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.4 mL of the dilutions. The cultures were incubated at 36±2°C with 5±1% CO_2 for a period of 4-6 days. The cultures were scored periodically for the presence of infectious virions upon completion of incubation. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

MRID # 479901-02	Results			Dried Virus Control ($TCID_{50}$/0.4mL)
		Lot No. Oct 4, 2009	Lot No. Sep 25, 2009	
Swine influenza A virus (H1N1)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.35}$
	$TCID_{50}$/0.4mL	$\leq 10^{1.1}$	$\leq 10^{1.1}$	
	Log Reduction	≥4.25	≥4.25	

VI. CONCLUSIONS

1. The submitted data (MRID 479900-01) support the use of the product, Anolite, as a hard surface disinfectant with virucidal activity against Swine influenza A virus (H1N1), at full strength in the presence of light organic soil at room temperature for a contact time of 10 minutes.

VII. LABEL

1. The proposed label claims that the product, Anolite, is an effective disinfectant against Swine influenza A virus (H1N1) in the presence of moderate organic soil (5% serum) at full strength with a contact time of 10 minutes on hard, nonporous surfaces. These claims are **acceptable** as they are **supported** by the submitted data.